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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Confirmation No. 3988

Appl. No. : 10/694,646
Applicants : Anuja Patel, Jianhau Yang
Filed : October 27, 2003
Art Unit : 3736
Examiner : George P. Wyszomierski
Title : LONG FATIGUE LIFE NITINOL

Docket No.: : PARCR-65197
Customer No. : 24201

DECLARATION OF CRAIG MAR UNDER 37 C.F.R. § 1.132

Dear Sir:

I, Craig Mar, hereby declare as follows:

1. I have taken over as reviewing engineer in place of the two named inventors who have left Paracor Medical, Inc., the assignee. I am skilled in metallurgy and the use of metals in medical devices.
2. I submit this declaration in support of applicant's Response to the final Office action mailed September 24, 2007, to overcome the examiner's rejections.
3. I am presently employed by Paracor Medical, Inc. My title is Principal Engineer. I am responsible for implantable product design at Paracor Medical, Inc.
4. I have a B.S. degree in Bioengineering from the University of California - Berkeley. My past design and engineering work involved looking at all metallurgical considerations for medical disposable and medical implant products such as guide wires,

angioplasty catheters, implantable pacing and defibrillator leads, implantable hearing devices, and other implantable cardiovascular devices.

5. In preparation for making this declaration, I reviewed the above-identified patent application, the pending claims, the final Office action mailed September 24, 2007, the cited prior art including U.S. Patent Application Publication No. US 2002/0005047 (Beard) for “Jewelry Including Shape Memory Elements.”

6. With this declaration, I would like to establish that the claims recite properties including, for example, the A(f) temperature at the ingot state, percent cold working, etc., are necessary to achieve the final wire’s material properties which in turn results in a high fatigue life nitinol. Also, I would like to establish that in view of the Beard published application jewelry wire, it would be highly unlikely for someone skilled in the art to produce a high fatigue life nitinol wire such as we have done and claimed in applicant’s patent application by referring to the data in the Beard patent alone, as the examiner has done.

7. From what I understand about nitinol (and metallurgy in general), the past processing history of the material does affect the later crystal structure, and crystal distribution and the impurity distribution in the material. This would in turn affect the A(f). Indeed, if the ingot A(f) temperature were not within the specified range (as defined in the claims), or the lower amount of cold work or other process steps not followed, then the final wire would not have the high fatigue properties as described in applicant’s patent application. Thus, properties or conditions in the past processing are present in the current condition or property of the nitinol material.

8. Although the percent amount of trace elements may be negligible, that does not mean that the trace elements do not have an effect. In fact, a small amount of trace elements can serve to lock in crystal structure, crystal size, or dislocation possibilities which would affect the A(f) and other material properties. Further, these impurities as

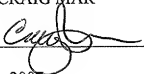
described in applicant's patent application can lead to actual inclusions that lead to failure when the material is cycled over and over, thus shortening the fatigue life.

9. Regarding the fatigue life, the "standard nitinol wires" referred to in applicant's specification at para. [0014] which failed after 16,560 cycles (rotary beam test) has similar properties and is similar to the nitinol wire referred to in the Beard patent application. By comparison, our devices are made from wires that are fatigue tested to show fatigue resistance (no failures, statistically significant) for greater than 380,000,000 cycles (based on a company internal test report dated January 2, 2004, where 30 of 30 samples were fatigue tested past 380,000,000 cycles with no failures). Thus, our fatigue life results are unexpectedly greater than the classical (Beard) treatment, and our claimed fatigue failure curve (plot of stress S versus N cycles to failure) does not behave in the classical manner.

10. The design requirements for a medical device and a medical device for implantation are not the same, nor are they obvious. The design requirements for a disposable syringe versus an implantable medical device, say a Left Ventricular Assist Device (LVAD), would be very different. Not only are the requirements for the implantable device much greater, but many of the requirements could only be found out by trial and error or hard experience. Therefore, it is my opinion that given the teaching of jewelry wire in Beard, that a person skilled in the art could then extrapolate and create a wire, ribbon or sheet of our claimed invention and make it suitable for an implantable medical device, would be a nearly impossible endeavor.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of inventor: CRAIG MAR

Declarant's signature: _____

Date: Nov. 19, 2007

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